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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/821,128	04/09/2004	Jun E. Lee	IVGN 373	8246	
65482 INVITROGEN	7590 09/05/200 CORPORATION	7	EXAMINER		
C/O INTELLEVATE			SISSON, BRADLEY L		
P.O. BOX 52050 MINNEAPOLIS, MN 55402			ART UNIT	PAPER NUMBER	
			1634		
			MAIL DATE	DELIVERY MODE	
			09/05/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<u> </u>		Application No.	Applicant(s)	
		10/821,128	LEE ET AL.	
	Office Action Summary	Examiner	Art Unit	
		/Bradley L. Sisson/	1634	
Period f	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address	
WHI - Exte afte - If N - Fail Any	HORTENED STATUTORY PERIOD FOR REPLY CHEVER IS LONGER, FROM THE MAILING DA ensions of time may be available under the provisions of 37 CFR 1.13 or SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period we ture to reply within the set or extended period for reply will, by statute, or reply received by the Office later than three months after the mailing ned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be timused and will expire SIX (6) MONTHS from a cause the application to become ABANDONE.	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).	
Status				
2a)	Responsive to communication(s) filed on <u>07 Mar</u> This action is FINAL . 2b) This Since this application is in condition for allowant closed in accordance with the practice under E	action is non-final. nce except for formal matters, pro		
Disposit	tion of Claims			
5)□ 6)⊠ 7)□	Claim(s) 1-15 and 32-82 is/are pending in the at 4a) Of the above claim(s) See Continuation She Claim(s) is/are allowed. Claim(s) 1,3,5,6,8,9,15,55,59,62,64,71,76 and Claim(s) is/are objected to. Claim(s) are subject to restriction and/or	eet is/are withdrawn from considence is/are withdrawn from considence is/are rejected.	eration.	
Applicat	tion Papers			
10)	The specification is objected to by the Examiner The drawing(s) filed on is/are: a) acce Applicant may not request that any objection to the o Replacement drawing sheet(s) including the correction The oath or declaration is objected to by the Examiner	epted or b) objected to by the Edrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).	
Priority (under 35 U.S.C. § 119			
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau See the attached detailed Office action for a list of	s have been received. s have been received in Application ity documents have been receive (PCT Rule 17.2(a)).	on No d in this National Stage	
•	<i>w</i> .			
Attachmen 1) Notice	nt(s) ce of References Cited (PTO-892)	4) Interview Summary	(PTO-413)	
2) Notic 3) Infor	ce of Neterlandes Oiled (170-032) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO/SB/08) er No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	te	

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,7,10-14,32-54,56-58,60,61,63,66-70,72-75,77 and 79-82.

Art Unit: 1634

DETAILED ACTION

Election/Restrictions

- 1. Applicant's election without traverse of Group I, with the following election of patentably distinct species, in the reply filed on 30 August 2006 is acknowledged. The patentably-distinct species elected are:
 - a. Template is present, and is a population of mRNA molecules;
 - b. No detectable label is present,
 - c. An enzyme with transcriptase activity is present; and
 - d. The modified nucleotide is also present, and is aminoallyl-dUTP.
- 2. While Group I originally comprised claims 1-31 and 55-71, the subsequent election of patentably distinct species narrowed Group I to the following claims: Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78. It is noted that claims 76 and 78 were added via amendment 07 May 2007.
- 3. Claims 16-31 were cancelled by the amendment of 15 February 2007.
- 4. Claims 2, 4, 7, 10-14, 32-54, 56-58, 60, 61, 63, 66-70, 72-75, 77, 79-82 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 30 August 2006.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1634

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 6. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- 7. Independent claims 1, 55, and 76 each make reference to the composition or kit comprising "monomeric deoxyribonucleoside triphosphates" (emphasis added). A nucleoside, by definition, lacks the phosphate group, while a nucleoside has a phosphate group.

 Consequently, it is less than clear just what applicant is intending by use of the expression "deoxyribonucleoside triphosphate." Claims 3, 5, 6, 8, 9, 15, 59, 62, 64, 71, and 78, which depend from said claims, fail to overcome this issue and are similarly rejected.
- 8. Claims 3, 5, and 59 recite the limitation "said modified nucleotides" in line 1. There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections - 35 USC § 103

- 9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.

Art Unit: 1634

2. Ascertaining the differences between the prior art and the claims at issue.

- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
- 12. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,709,815 B1 (Doug et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).
- 13. For purposes of examination, the expression "monomeric deoxyribonucleoside triphosphates" has been construed to mean "monomeric deoxyribonucleotide triphosphates"
- 14. Doug et al., column 44, last paragraph, bridging to column 45, disclose a method by which PCR as well as RT-PCR is performed using mRNA as a template. Doug et al., also disclose that the reaction can be one that incorporates any combination of modified nucleotides. The aspect of Doug et al., performing RT-PCR speaks directly to the presence of an enzyme with reverse transcriptase activity.
- 15. While Doug et al., has been found to disclose using various analogs, including dUTP, they have not been found to teach the use of aminoallyl-dUTP.

Art Unit: 1634

16. Fischer et al., column 49, fourth paragraph, discloses using aminoallyl-dUTP in an assay that utilized a reverse transcriptase and mRNA.

- 17. It is further noted that the reagents, including the aminoallyl-dUTP, were provided in a kit.
- 18. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Doug et al., by incorporating aminoallyl-dUTP into same, as disclosed by Fischer et al., as Fischer et al., teaches explicitly of using such to produce transcripts of mRNA and that such can also be provided in a kit.
- 19. In view of the detailed teachings, and advanced state of the art, said ordinary artisan would have had a most reasonable expectation of success.
- 20. Accordingly, and in the absence of convincing evidence to the contrary, claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,709,815 B1 (Doug et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).

Conclusion

- 21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.
- 22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/821,128

Art Unit: 1634

23. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

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like assistance from a USPTO Customer Service Representative or access to the automated

information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/ Primary Examiner Art Unit 1634 Page 6

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